Patent Docket P1363R1

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of

Ansaldi et al.

Serial No.: 09/320,10

Filed:

May 26 1999

For: SEPARATION OF POLYPEPTIDE

MONOMERS

Group Art Unit: 1642

Examiner: Jennifer Nichols

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner of Patents, Washington, D.C. 20231 on

July 1, 2000

Pamela Gavette

AMENDMENT PURSUANT TO 37 CFR §1.111

Commissioner for Patents Washington, D.C. 20231

AUG 03 2000

Sir:

This is in response to the Office Action mailed December 8, 1999, and remailed with a resetting of the clock on March 1, 2000. Enclosed is a Petition and Fee to extend the period for response two months until August 1, 2000. Please amend the above-identified application as follows:

## IN THE CLAIMS:

- 1. (Amended) A method [is disclosed] for separating a polypeptide monomer from a mixture comprising monomers and dimers or multimers or both, wherein the method [comprises] consists essentially of applying the mixture to a cation-exchange or anion-exchange chromatography resin in a buffer, wherein if the resin is cation-exchange, the pH of the buffer is about 4-7, and wherein if the resin is anion-exchange, the pH of the buffer is about 6-9, and eluting the mixture at a gradient of about 0-1 M of an elution salt, wherein the monomer is separated from the dimers or multimers or both present in the mixture, and wherein the separated monomer has a purity of greater than 99.5% and the monomer yield is greater than 90%.
- 2. (Amended) The method of claim 1 wherein the polypeptide is [an antibody or] a serum albumin.
- 3. (Amended) The method of claim [2] 1 wherein the [antibody] polypeptide is anti-IgE, anti-IgG, anti-Her-2, anti-CD11a, anti-CD18, anti-CD20, [or] anti-VEGF, or IgE.

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